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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,196	07/23/2003	Guido Guglielmi	03-276 (US01)	1254

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EXAMINER	
YABUT, DIANE D	

ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
12/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,196	GUGLIELMI ET AL.	
	Examiner	Art Unit	
	DIANE YABUT	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-52,54,55,57 and 59-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-52,54,55,57 and 59-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is in response to applicant's amendment received on 08/05/2009.

The examiner acknowledges the amendments made to the claims.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on 12/16/2009 is acknowledged The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 29-35, 38, 43-52, 54, 59-61, 64-65, and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**).

Claims 29-35, 38, 43-45, 47, 54, 59-61, 64-65, and 72: Wheelock et al. disclose a system for positioning a vaso-occlusive implant in the body comprising a catheter **500** having a proximal end and a distal end, the catheter being insertable within a vascular cavity in the body, a delivery member or tubular core wire **100**, an insulative member **216**, a temporary connection **300** comprising an electrolytic connection joined to a distal

end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant (see abstract, Figures 1A-1C, 6A-6C; cols. 5-6). The electrolytic connection is exposed to the blood in a vascular cavity and is corroded by a power supply that provides an electrical current through the delivery member (col. 3, lines 39-46). The coil may consist of platinum (col. 9, lines 4-6).

Wheelock et al. does not disclose an electrical measurement device that is configured to monitor an electrical condition, such as impedance, related to the position of the temporary connection while the temporary connection is joined to the delivery member and the implant or the temporary connection being breakable by heat.

Ogawa et al. teach a system for positioning an implant in the body comprising an electrical measurement device ("power supply") **24**, wherein when a catheter **20** is inserted within the vascular cavity, the electrical measurement device is configured to monitor an electrical condition ("impedance reducing phenomenon") related to a position of a temporary connection **15** while the temporary connection is joined to the delivery member and joined to the implant, the electrical condition changing when the temporary connection, joined to the implant, reaches a predetermined location at or beyond the distal end of the catheter as the delivery member is advanced through the catheter, the electrical measurement device configured to generate an output signal (by monitoring the magnitude of impedance between the delivery wire and the electrical measurement device) while the temporary connection is joined to the implant and in response to the changed electrical condition, the output signal indicating the temporary connection,

joined to the implant, has reached the predetermined location, and subsequently allowing the user to initiate breaking of the temporary connection by application of heat and releasing the implant (see abstract, Figures 4-5, col. 6, lines 34-61, col. 7, line 54 to col. 8, line 15, col. 9, lines 35-52). Also disclosed is a visual indicator or output signal (monitored change in impedance) is indicated to the user after the electrical condition has changed while the implant is joined to the temporary connection (col. 7, line 54 to col. 8 line 6 and col. 10, lines 30-52). The guide wire **10** is conductive and positioned between the catheter and the electrical measurement device/power source (see abstract and Figure 5).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide an electrical measurement device, as taught by Ogawa et al., to Wheelock et al. in order to detect with high reliability a state that the implanted device is deposited properly at an intended site before severing the temporary connection (col. 3, lines 65-67).

Claims 46 and 48-52: Although neither Wheelock et al. nor Ogawa et al. teach the coil having a bio-reactive material coating or the coil being a non-bio-reactive polymer coil (however teaching that the implant "may carry or hold suitable substances," in Ogawa, col. 6, lines 59-61), it would have been obvious to one of ordinary skill in the art to provide the claimed materials, since it was known in the art that a coating of bio-reactive material may aid in the endovascular embolism or occlusion and non-bio-reactive polymer coils can remain longer within the body without having to be surgically removed. The implant being a stent or a filter is also not expressly disclosed. However,

it would have been obvious to one of ordinary skill in the art to provide a stent or a filter as the implant, since it was known in the art that vaso-occlusion is commonly achieved by filters and stents. Wheelock et al. also recognizes GDC coils with stainless steel detachable connections being old and well known in the art (col. 2, line 32 to col. 3, line 17).

3. Claims 36, 41-42, 55, 57, and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Scheldrup et al.** (U.S. Patent No. **5,669,905**).

Claims 36: Wheelock et al. and Ogawa et al. disclose the claimed device except for the electrical monitoring device being separate with the power supply.

Scheldrup et al. teach an electrical monitoring device **300** being included with the power supply that provides DC power (Figure 6).

It would have been obvious to one of ordinary skill in the art at the time of invention to provide the electrical monitoring device separate from the power supply, as taught by Scheldrup et al., since applicant has not specifically disclosed that having them separate solves any stated problem or is for any particular purpose and it appears that the combined device of Wheelock et al. and Ogawa et al. would perform equally well with the this configuration.

Claims 41-42: Wheelock et al. and Ogawa et al. disclose the claimed device except for the electrical condition comprising a current or voltage.

Scheldrup et al. teach that current may be monitored as an electrical condition when positioning an implant (col. 12, lines 42-46). It would have been obvious to one of ordinary skill in the art at the time of invention to monitor current as an electrical condition, as taught by Scheldrup, to Ogawa in order to effectively detach an implant from an electrolytic connection and generate an output signal.

Claims 55, 57, and 66: Wheelock et al. and Ogawa et al. disclose the claimed device, except for an audio indicator, a controller, and the electrical monitoring device comprising a volt/current meter.

Scheldrup teaches an audio indicator, an electrical measurement device being configured to provide the output signal to the audio indicator so that the audio indicator can be activated after an electrical condition has changed (col. 10, lines 30-44) and the electrical monitoring device comprising a volt/current meter (Figures 4-6). Scheldrup also teaches an output signal being provided to a controller **300**, the electrical measurement device being configured to provide the output signal to the controller, the controller being configured to automatically break the temporary connection in response to the output signal after the electrical condition has changed (Figure 6, col. 8, lines 40-49). It would have been obvious to one of ordinary skill in the art at the time of invention to provide an audio indicator and volt/current meter and controller, as taught by Scheldrup, to Wheelock et al. and Ogawa et al. in order to facilitate signaling to the physician when positioning the implant.

4. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Palermo** (U.S. Patent No. **5,250,071**).

Claim 37: Wheelock et al. and Ogawa et al. disclose the claimed device, except for the temporary connection being mechanical.

Palermo teaches an embolic coil with a temporary mechanical connection (col. 2, line 63 to col. 3, line 18). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the temporary connection of Wheelock et al. and Ogawa et al. by providing a mechanical connection, as taught by Palermo, since it was known in the art that temporary mechanical connections are old and common in detachable surgical implants that extend to filters and stents.

5. Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Guglielmi et al.** (U.S. Patent No. **5,569,245**).

Claim 39: Wheelock et al. and Ogawa et al. disclose the claimed device, as discussed above, except for the temporary connection comprising a temporary connection that is breakable by application of radio frequency (RF) radiation.

Guglielmi et al. teach a temporary connection that is breakable by application of radio frequency (RF) radiation (col. 3, lines 10-20). It would have been obvious to one of ordinary skill in the art to provide a temporary connection broken by heat and RF radiation, as taught by Guglielmi et al., to Wheelock et al. and Ogawa et al., since it was known in the art that RF radiation is an effective detachment sources and commonly breaks connections, joints, or attachments in surgical devices.

6. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Sepetka et al.** (U.S. Patent No. **5,814,062**).

Claim 40: Wheelock et al. and Ogawa et al. disclose the claimed device, except for the temporary connection comprising a temporary connection that is hydraulically broken.

Sepetka et al. teach a temporary connection that is hydraulically broken (col. 3, lines 10-26). It would have been obvious to one of ordinary skill in the art to provide a temporary connection that is hydraulically broken, as taught by Sepetka, to Wheelock et al. and Ogawa et al., since it was known in the art that fluid pressure is commonly used to disconnect temporary detachments between embolic coils and delivery members.

7. Claims 62-63 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**), as applied to claim 29 above, and further in view of **Cheng et al.** (U.S. Patent No. **6,296,636**).

Claims 62-63: Wheelock et al. and Ogawa et al. disclose the claimed device, as discussed above, except for comparing a reference current with a second current that is generated, the second current being larger than the reference current, or the electrical measurement device including a comparison circuit, the comparison circuit being configured to compare a threshold current to a current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal the measured current is larger than the threshold current.

Cheng et al. teach an electrical measurement device including a current measurement device configured to monitor the electrical current and a comparison circuit, the comparison circuit being configured to compare a threshold current to a current measured by the electrical measurement device, the comparison circuit being further configured to generate the output signal when the temporary connection has reached the predetermined location and the measured current is larger than the threshold current – the output indicating limiting power (col. 5, lines 15-34). Limiting power during electrosurgery avoids overcurrent or sparks that may occur, which is effectively prompted by using reference and measured currents (col. 3, lines 48-55). It would have been obvious to one of ordinary skill in the art at the time of invention to

modify Wheelock et al. and Ogawa et al. by providing a comparison circuit, as taught by Cheng et al., in order to obtain a desired output signal, which may limit power during electrosurgery to avoid overcurrents or sparks, which is effectively prompted by using reference and measured currents.

8. Claims 67-71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wheelock et al.** (U.S. Patent No. **6,077,260**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**) and **Scheldrup et al.** (U.S. Patent No. **5,669,905**).

Claims 67-71 and 73: Wheelock et al. disclose a system for positioning a vaso-occlusive implant in the body comprising a catheter **500** having a proximal end and a distal end, the catheter being insertable within a vascular cavity in the body, a delivery member or tubular core wire **100**, an insulative member **216**, a temporary connection **300** comprising an electrolytic connection joined to a distal end of the delivery member, the insulative member being positioned between and connecting the temporary connection and the implant (see abstract, Figures 1A-1C, 6A-6C; cols. 5-6). The electrolytic connection is exposed to the blood in a vascular cavity and is corroded by a power supply that provides an electrical current through the delivery member (col. 3, lines 39-46). The coil may consist of platinum (col. 9, lines 4-6).

However, Wheelock et al. does not disclose an electrical measurement device that is configured to monitor an electrical condition, related to the position of the temporary connection while the temporary connection is joined to the delivery member and the implant.

As discussed above, Ogawa et al. teach an electrical measurement device configured to monitor impedance (see paragraph 2 above). In addition, Scheldrup et al. teach that current levels may be monitored as an electrical condition (col. 12, lines 42-46 and paragraph 3 above). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Wheelock et al. with electrical monitoring devices, as taught by Ogawa et al. and Scheldrup et al., in order to reliably and effectively detach an implant from an electrolytic connection and generate an output signal at a specific location.

9. Claims 29, 74, 76, 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wallace et al.** (U.S. Patent No. **5,941,888**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**).

Wallace et al. disclose a system for positioning an implant **212** comprising a catheter **208** having a proximal end and a distal end, the catheter being insertable within a vascular cavity in the body, a delivery member **228**, an insulative member ("insulative joint") **222**, a temporary connection ("disintegratible link") **224** joined to a distal end of the delivery member, the insulative member extending between and connecting a distal end of the temporary connection and a proximal end of the implant (Figure 2). The insulative member prevents or minimizes the amount of current that flows through the delivery member when the delivery member is within the catheter, and the temporary connection is insulated from the implant so that the electrical current passes to the

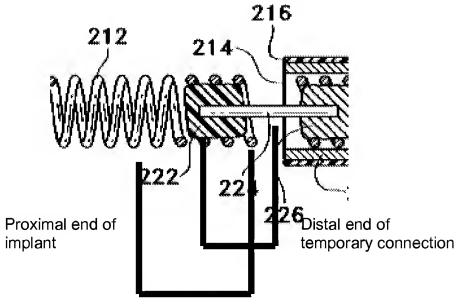

FIG. 2

temporary connection but not the implant (col. 6, lines 5-15).

Wallace et al. disclose the claimed device except for an electrical measurement device that is configured to monitor an electrical condition, related to the position of the temporary connection while the temporary connection is joined to the delivery member and the implant.

As discussed above, Ogawa et al. teach an electrical measurement device configured to monitor impedance (see paragraph 2 above). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Wallace et al. with electrical monitoring devices, as taught by Ogawa et al., in order to reliably and

effectively detach an implant from an electrolytic connection and generate an output signal at a specific location.

9. Claims 67, 75, 77, 79 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Wallace et al.** (U.S. Patent No. **5,941,888**) in view of **Ogawa et al.** (U.S. Patent No. **5,846,210**) and **Scheldrup et al.** (U.S. Patent No. **5,669,905**).

Wallace et al. disclose a system for positioning an implant **212** comprising a catheter **208** having a proximal end and a distal end, the catheter being insertable within a vascular cavity in the body, a delivery member **228**, an insulative member ("insulative joint") **222**, a temporary connection ("disintegratible link") **224** joined to a distal end of the delivery member, the insulative member extending between and connecting a distal end of the temporary connection and a proximal end of the implant (Figure 2). The insulative member prevents or minimizes the amount of current that flows through the delivery member when the delivery member is within the catheter, and the temporary connection is insulated from the implant so that the electrical current passes to the temporary connection but not the implant (col. 6, lines 5-15).

Wallace et al. disclose the claimed device except for an electrical measurement device that is configured to monitor an electrical condition, related to the position of the temporary connection while the temporary connection is joined to the delivery member and the implant.

As discussed above, Ogawa et al. teach an electrical measurement device configured to monitor impedance (see paragraph 2 above). In addition, Scheldrup et al.

teach that current levels may be monitored as an electrical condition (col. 12, lines 42-46 and paragraph 3 above). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Wallace et al. with electrical monitoring devices, as taught by Ogawa et al. and Scheldrup et al., in order to reliably and effectively detach an implant from an electrolytic connection and generate an output signal at a specific location.

Response to Arguments

10. Applicant's arguments filed 08/05/2009 have been fully considered but they are not persuasive.

11. Applicant generally argues that Wheelock does not disclose an insulative member **216** being positioned between and connecting the implant **218** and the temporary connection **300**, but rather the insulative member is part of the coil implant and is not intended to be positioned between or connecting the temporary connection and the implant. Although there is overlap between the implant **218** and the insulating layer **216**, the insulating is still considered to be positioned and connected between the implant and the temporary connection since it resides in a space separating a distal portion of the implant and a distal portion of the temporary connection, and therefore reads on the limitation. In addition, applicant argues that Ogawa does not teach this limitation, which is conceded by the examiner.

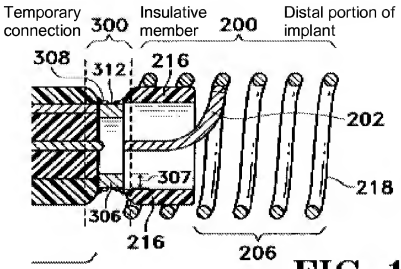

FIG. 1A

12. Applicant also requests identification the sections of the prior art that allegedly disclose the limitation of the conductive wire being connected between the electrical measurement device and the distal end of the catheter, the electrical measurement device being configured to detect an electrical condition related to a position of the temporary connection while joined to the implant in the catheter through the conductive wire, the conductive wire being positioned through the catheter. The limitation is described in paragraph 2 above, wherein Ogawa teaches a conductive guide wire **10** (high-frequency current can be applied to guidewire – col. 6, lines 28-39) which is connected between an electrical measurement device ("power supply") **24** and the distal end of a catheter **20**, the electrical measurement device being configured to monitor an electrical condition ("impedance reducing phenomenon") related to a position of a temporary connection **15** while joined to the implant in the catheter through the

conductive wire, the conductive wire being positioned through the catheter (Figures 4-5; col. 7, line 54 to col. 8, line 2).

13. In addition, the applicant requests clarification of where Ogawa teaches the output signal being provided to the user while the temporary connection is joined to the implant, to allow the user to manually initiate breaking of the temporary connection and to release the implant. In col. 7, line 54 to col. 8, line 6 Ogawa teaches that an output signal is provided to the user by the power source **24** which is at a terminal part of the guide wire when the temporary connection **15** joined to the implant **16** reaches a location at a distal end of the catheter **20**. At that point, "high-frequency current for detaching the implanted device is applied between the guide wire **10** and the counter electrode **23** by the high frequency power source **24**." The implant may be safely "pulled back" (col. 8, lines 30-34 and 56-58) without breaking the joint member to ensure proper positioning of the implant before application of the high frequency current by the high power source. The ensured and high reliable positioning of the implanted device is considered to be the user manually initiating the breaking of the temporary connection while the temporary connection is still joined to the implant and provides an output signal to the user, since proper positioning is required before application of the high frequency current.

14. Applicant's arguments with respect to claims 74-79 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIANE YABUT whose telephone number is (571)272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Diane Yabut/
Examiner, Art Unit 3734

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3734